REMARKS

Applicant traverses the rejections of claims 1-3, 5-9, 11-14, 27-31, 34, 36 and 37 as being unpatentable under 35 U.S.C. 103(a) over Boyce et al. 5,899,939 and claims 4, 10, 15-26, 32, 33 and 35 as being unpatentable by combining Boyce et al. '939 with Boyce et al. 6,294,187.

The present invention is a bone sheet taken from a singular tubular bone under the method claimed in claim 34 using both the cortical and cancellous portions of the tubular bone which naturally occur to form the bone sheet. The portions are partially demineralized, leaving a single integral sheet having residual calcium content of a specified range for surgical usage. Previously, it had been believed that the cancellous layer portion of a bone could not be used in a structural device and bone sheets were to be taken from cortical bone, demineralized and glued together. Since there is a shortage of donors it is imperative that donor bone be used as efficiently as possible. The present invention thus provides for a more efficient use of natural existing bone to obtain maximum material use.

The Boyce et al '939 reference is a bone derived implant of a composite structure which is made up of at least two superimposed layers of fully mineralized or demineralized or partially demineralized cortical bone material adhesively secured or fastened to each other to form a single rigid structure which was then cut into shaped implants. The implant structure is constructed after demineralization has been undertaken and no amounts of demineralization of the structure have been disclosed. It is not made from a single piece of formed bone. While the Examiner has characterized Boyce '939 as comprising a unified structure of two or more layers includes a demineralized cortical layer and another layer of a different material, this does not teach the second layer to be cancellous.

The cited paragraphs of Boyce '939 do not teach the present invention. The implant of Boyce et al. '939 is described as noted on Column 5 lines 62-65, "the cortical portion of bone 10 taken from the diaphyseal region is cut into cortical bone layers 11 of varying width by slicing the bone longitudinally". These sections are optionally demineralized. Depending on the thickness of the layers of the composite structure, which are adhesively secured together, can be anywhere from 2 to 200 layers overall, with a thickness ranging from about 0.5 to about 20 mm. A specific overall compression strength for the implant of from about 25 to about 250 Mpa can be obtained. The layers are held together through the use of biological compatible adhesives and mechanical fasteners such as pins, screws, dowels. Figure 2 illustrates an implant comprising alternating layers of fully mineralized cortical bone and partially demineralized cortical bone. Furthermore, there is no discussion of the amount of demineralization and layers are fully mineralized to keep the compression strength of the implant. Example 1 is directed toward slices of mineralized bone and Example 2 is directed toward half of the slices being fully demineralized. As noted in Examples 1 and 2, the slices are held together with cyanoacrylate adhesive. Example 3 is directed to longitudinally cut fully mineralized bars arranged in a lattice structure. In short all that this reference teaches is the assembly of layers of cut cortical bone which are adhesively held together to provide a layered assembly which is then cut into the desired shape. This does not approach or begin to teach the present invention. The Boyce et al. '939 reference teaches away from the present invention.

Furthermore, Boyce et al. '939 does not teach residual calcium left after demineralization because the bone is fully demineralized to achieve osteoinductiveness. The Examiner's response that routine or manipulative experimentation could obtain the ranges of residual calcium are without merit. Technical studies have shown that residual calcium has a benefit in the bone healing process.

The Boyce '187 patent simply teaches an osteoimplant bone composition formed of shaped compressed bone particles. These powdered bone particles range in average particle size from about 0.05 to about 1.2 cm in size and all obtained by milling or shaving the surface of an entire bone with at least 60% of the bone particles being elongated. Compressive forces of from about 2,500 to 60,000 psi are applied to bone particles in a mold to produce a hard chalk-like material. There is no teaching using a layer of cancellous bone as part of a bone sheet in a continuous integral sheet of bone used for surgical repair. Indeed, the prevailing view was that only cortical bone could be used for strength reasons. However, it has been found that cancellous bone can be used and that it has excellent osteoinductive properties. The reference does not teach or suggest the present invention which has a continuous sheet of demineralized bone with a cortical and cancellous layer taken from a single bone.

The court in *Minnesota Mining & Manufacturing Co. v. Johnson &Johnson Orthopaedics, Inc.*, 24 USPQ2d 1321 (Fed. Cir 1992) held that: "Although [a patent's] specific claims are subsumed in [a prior art reference's] generalized disclosure..., this is not literal identity." The *Minnesota* court held that the reference's ranges were so broad as to be meaningless, and provided no guidance on how to construct a product with the patented invention's benefits. Such is true in the present case. The court in *In re Baird,* 29 USPQ2d 1550 (Fed. Cir. 1994) held that "The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious." The *Baird* court further held that a disclosure to numerous compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds.

Applicants would thus submit that the cited references singularly or in combination do not

teach or obviate the present invention and that the application should be allowed and be passed to issue. There is no teaching of the cancellous and cortical layers and no teaching of the cancellous cortical interface section. There is also no teaching of the method claimed.

The Examiner's continued rejection of the present invention as double patenting in view of claims 1 and 4 of U.S. Patent Number 6,326,018 B1 is again traversed as the '018 patent is directed toward a totally different invention. The '018 patent is comprised of small demineralized bone particles ranging in size from 250 to about 850 microns and a carrier which is lyophilized to remove the water component leaving a flexible static sheet of bone particles. Claims 4 is the addition of a calcium salt which has nothing to do with residual calcium which is left by not completely demineralizing the bone.

An Extension of Time for Three Months and Notice of Appeal together with payments of same is attached is filed simultaneously. If any additional costs are incurred, please charge Deposit Account Number 07-1340.

It is respectfully requested that the arguments in the present application in condition for favorable reexamination and that the application should be allowed and passed to issue.

Respectfully submitted,

GIPPLE & HALE

John S. Hale
Registration No. 25,209

6665-A Old Dominion Drive
McLean, Virginia 22101
(703) 448-1770 ext. 304
Attorney Reference: X-9338